DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 9, 2015

Biofilm, Inc.
Sherry Castello
Regulatory Affairs and Quality Assurance Associate
3225 Executive Ridge
Vista, CA 92081

Re: K141132
Trade/Device Name: Astroglide TTC Fertility Friendly Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: PEB
Dated: November 24, 2014
Received: November 25, 2014

Dear Sherry Castello,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141132

Device Name
Astroglide TTC Fertility Friendly Personal Lubricant

Indications for Use *(Describe)*
Astroglide® TTC is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Astroglide TTC is compatible with sperm, oocytes, and embryos and can be used by couples trying to conceive. Astroglide® TTC is compatible with natural rubber latex, polyisoprene and polyurethane condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Astroglide TTC Fertility Friendly Personal Lubricant

i. **General Information on Submitter**

Applicant:	BioFilm, Inc.
Address:	3225 Executive Ridge Vista, CA 92081 USA
Telephone:	760-727-9030
Fax:	760-727-8080
Contact Person:	Sherry Castello
Email:	sherry@biofilm.com
Date Prepared:	November 24, 2014
Establishment Registration:	2025771

ii. **General Information on Device**

Proprietary Name:	**Astroglide® TTC Fertility Friendly Personal Lubricant**
510(k) Number:	**K141132**
Common Name:	Personal Lubricant
Classification Name:	Lubricant, Personal, Gamete, Fertilization, and Embryo Compatible (21 CFR 884.5300, Condom), product code: PEB

iii. **Predicate Device**

Pre-Va Vaginal Lubricant, K072741, manufactured by INGFertility, LLC

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iv. **Description of Device**

Astroglide® TTC Fertility Friendly Personal Lubricant is a non-sterile, clear, and water-based personal lubricant for penile and/or vaginal application. Astroglide® TTC has a pH and osmolarity that is compatible with sperm survival and migration. The device is packaged in pre-filled tube applicators which may be used for single use intra-vaginal application or applied directly to penis or vagina.

Astroglide® TTC is formulated using water, propylene glycol, hydroxyethylcellulose, fructose, methylparaben, sodium phosphate, potassium phosphate, propyl paraben, galactose, and sodium hydroxide.

This device is batch lot tested for appearance, color, clarity, odor, viscosity, pH, microbial count, osmolality, endotoxin, mouse embryo assay and human sperm survival assay.

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v. **Indications for Use**

Astroglide® TTC is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Astroglide TTC is compatible with sperm, oocytes, and embryos and can be used by couples trying to conceive. Astroglide® TTC is compatible with natural rubber latex, polyisoprene and polyurethane condoms.

vi. **Technological Characteristics of Astroglide® TTC Compared to Predicate**

Technological Characteristics of Astroglide TTC and the predicate are very similar. Any minor technological differences noted do not affect the safety or effectiveness of the device.

Attribute	**TTC, Fertility Friendly Personal Lubricant**	**Predicate: Pre-Va Vaginal Lubricant**
510(k)	**K141132**	**K072741**
Indications for use	Astroglide® TTC is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Astroglide TTC is compatible with sperm, oocytes, and embryos and can be used by couples trying to conceive. Astroglide® TTC is compatible with natural rubber latex, polyisoprene and polyurethane condoms.	• To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre-Va may be applied directly to the device or may be deposited intravaginally using the applicator prior to the insertion of diagnostic or therapeutic devices used in fertility interventions. • As a personal lubricant Pre-Va supplements the body's own natural lubrication fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. Pre-Va is safe for use by couples who are trying to conceive and may be applied to vaginal or penile tissues for lubrication and

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Attribute	TTC, Fertility Friendly Personal Lubricant	Predicate: Pre-Va Vaginal Lubricant
		moisturization purposes. It is compatible with latex and polyurethane condoms.
Ingredients	Water, Propylene Glycol, Hydroxyethylcellulose, Fructose, Methylparaben, Sodium Phosphate, Potassium Phosphate, Propyl Paraben, Galactose, Sodium Hydroxide	Water, Hydroxyethylcellulose, Pluronic 127, Sodium Chloride, Arabinogalactan, Sodium Phosphate, Carbopol 934P, Methyl Paraben, Sodium Hydroxide, Potassium Phosphate
Method of Application	Directly by hand or intra-vaginally with pre-filled tube applicator	Directly from tube or with separate disposable applicator
Storage Instruction	36°F to 86°F	36°F to 86°F
pH	7.2-7.6	7.20-7.45
Osmolarity	220-400 mOsm/kg	260 to 370 mOsm/kg
Endotoxin by LAL methodology	≤0.7 EU/mL	≤0.7 EU/mL
Mouse Embryo Assay (MEA)	Using 1-cell MEA exposed to 10% solution for 30 minutes >80% expanded blastocysts at 96 hrs.	Using 1-cell MEA exposed to 5% solution for 30 minutes, >80% expanded blastocysts at 96 hrs.
Human Sperm Survival Assay (HSSA)	After exposure to 10% TTC for 2 hours, ≥80% of the control.	After exposure to 10% Pre-Va for 30 min, ≥80% of the control.
Condom Compatibility	Compatible with latex, polyurethane, and polyisoprene condoms	Compatible with latex and polyurethane condoms.

vii. **Summary of Performance Data**

Lubricant barrier assays performed on Astroglide® TTC demonstrated that the properties of the device do not impede sperm penetration into the lubricant. Mouse *In vitro* fertilization assays in combination with Mouse embryo assays (IVF-MEA) demonstrated normal fertilization and embryo development with no suggestion of toxicity. Mucosal penetration studies using a hyaluronic acid (that mimics cervical mucus) indicate that the "swim-up" ability of sperm exposed to Astroglide TTC is not affected. Computer Assisted Sperm Analysis demonstrates the progressive motility of sperm is not harmed by Astroglide TTC. DNA integrity testing after exposure to Astroglide TTC demonstrated the device does not harm human sperm chromatin (DNA). Sperm penetration assays (hamster zona-free ovum tests) demonstrated that the presence of Astroglide TTC did not affect the penetration of hamster ova by human sperm.

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Condom compatibility studies indicate that TTC is safe to use with natural rubber latex, polyisoprene, and polyurethane condoms.

Biocompatibility tests and results are shown in the table below:

Biocompatibility Testing	**Astroglide TTC Result**
Cytotoxicity, Direct Contact, ISO 10993-5, formula	The test article was not considered to have a cytotoxic effect.
Guinea Pig Maximization, ISO 10993-10, formula	The test article did not elicit sensitization reactions.
Vaginal Irritation, ISO 10993-10, formula	The test article was considered non-irritating to the vaginal mucosa in New Zealand White Rabbits.
Systemic Toxicity, ISO 10993-11, formula	Test article met the requirements of ISO 10993-11. No test animals exhibited any biological reactivity.
Cytotoxicity, MEM Elution, ISO 10993-5, applicator tube	The test article was not considered to have a cytotoxic effect.
Guinea Pig Maximization, ISO 10993-10, applicator tube	The test article did not elicit sensitization reactions.
Vaginal Irritation, ISO 10993-10, applicator tube	In New Zealand White Rabbits, the test article when extracted in saline was considered minimally irritating. The test article when extracted in cottonseed oil was considered non-irritating.

On-going stability studies show the device has met acceptance criteria for appearance, color, clarity, odor, viscosity, pH, microbial count, osmolality, endotoxin, mouse embryo assay, and human sperm survival assay for an 8 month shelf-life. Antimicrobial effectiveness testing has been performed and the preservative system is effective.

The performance data concludes that Astroglide® TTC is substantially equivalent to the predicate device Pre-Va Vaginal Lubricant. Astroglide® TTC does not harm sperm, oocytes, or embryos and is safe for use by couples trying to conceive.

viii. **Conclusion**

The proposed and predicate indication statements do not represent a new intended use. Astroglide® TTC personal lubricant has the same intended use as PreVa for use in a non-clinical environment. The technological characteristics of Astroglide TTC and the predicate are very similar. Any minor technological differences noted do not affect the safety or efficacy of the device. Performance testing demonstrates that Astroglide TTC does not harm sperm, oocytes, or embryos and is safe to use by couples trying to conceive.